DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 7, 2015

Medspira, LLC
Jim Quackenbush
CEO
2718 Summer Street N.E.
Minneapolis, MN 55413

Re: K143031
Trade/Device Name: mcompass Biofeedback Anorectal Manometry System
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: II
Product Code: KLA, HCC
Dated: May 27, 2015
Received: June 1, 2015

Dear Jim Quackenbush,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143031

Device Name
mcompass Biofeedback Anorectal Manometry System

Indications for Use *(Describe)*
The mcompass Biofeedback Anorectal Manometry System is for use on patients requiring anorectal pressure studies and biofeedback therapy.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5.0 510(k) Summary

Submitter:	Medspira, LLC 2718 Summer Street NE Minneapolis, MN 55413
Contact Person:	Jim Quackenbush Chief Executive Officer Telephone: 763-244-1079 Fax: 612-789-2708 Email: jquackenbush@medspira.com
Date Prepared:	October 17, 2014
Trade Name:	*mcompass*™ Biofeedback Anorectal Manometry System
Common Name:	Gastrointestinal monitoring system
Classification Name:	Gastrointestinal motility monitoring system (21 CFR 876.1725)
Regulatory Class:	II
Product Code:	KLA, HCC
Predicate Device:	*mcompass* Anorectal Manometry System (K120088) *This device has not been subject to a design-related recall.*
Device Description:	The *mcompass* Biofeedback Anorectal Manometry System is a manometry system for the measurement of anorectal pressures. It provides visual feedback (biofeedback) of the muscle action allowing the patient to modulate the activity of the anorectal muscles, thereby reeducating the pelvic floor muscles. It is used in a clinical setting and consists of a non-sterile disposable catheter (2-channel or 5-channel), a previously cleared reusable RMD FOB (and related battery charger), and software that resides on a tablet PC and that collects, records and displays the pressure data. Air-charged balloons are used to measure contractile pressures of the anorectal canal and simulate a range of bowel fullness levels, in addition to measuring locational pressure at the distal tip of the catheter. During the clinical procedure, the distal end of the catheter is inserted in the anus/rectum of the patient. The proximal end of the catheter is connected via an integrated cable to the handheld RMD FOB which transmits real-time pressure data wirelessly to the *mcompass* software on the PC.

Indications for Use:	The *mcompass* Biofeedback Anorectal Manometry System is for use on patients requiring anorectal pressure studies and biofeedback therapy.
Comparison of the Technological Characteristics with the Predicate Device:	The subject device is identical to the predicate device in the following ways: • Each of the devices is intended to measure anorectal pressures. • Each of the devices has separate channels for measuring anal canal pressures and distal rectal pressures. • Each of the devices uses air-charged (i.e. air-filled) measurement balloons. • Each of the devices has a urethane rectal balloon that is filled with air and measures distal rectal locational pressure. • Each of the devices has markings to indicate catheter insertion depth. • Each of the devices is sold non-sterile. • Each of the devices is a single use device (not to be sterilized or reused). The following technological differences exist between the subject device and the predicate device: • Configuration of the measurement balloons • Rectal balloon positioning • Working length • Biofeedback User software
Performance Data:	**Biocompatibility** The catheter is considered surface contacting (mucosal membranes) for a duration of less than 24 hours (limited exposure) and meets the following: • Cytotoxicity (Elution Test) per ISO 10993-5 • Systemic Toxicity per ISO 10993-11 • Intracutaneous Injection Test (Irritation) per ISO 10993-10 • Kligman Maximization Test (Sensitivity) per ISO 10993-10 • Neutral Red Uptake Cytotoxicity Test per ISO 10993-5 **Mechanical Testing** • Physical characteristics • System leak pressure • Burst pressure • Connector forces

	Electrical safety and Electromagnetic Compatibility (EMC) The electrical components of the *mcompass* Biofeedback Anorectal Manometry System meet the current standards for electrical safety and EMC. **Software Verification and Validation Testing** Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 2005).
Conclusion:	The information submitted in this premarket notification demonstrates that the *mcompass* Biofeedback Anorectal Manometry System performs as intended in the specified use conditions and supports the determination that the device is substantially equivalent in principles of operation, technology, materials and indications for use to the predicate device listed above.